



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,621	07/18/2003	Jan Weber	S63.2-10856-US01	2650
499 7590 12/24/2008 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
KOHARSKI, CHRISTOPHER				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
12/24/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/622,621

Applicant(s)

WEBER ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/14/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-38 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 38 and 63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 07/14/2008 in which claims 32, 63 and 65 were amended. Currently claims 27-38 and 63-68 are pending for examination in this application.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. See MPEP 606.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-29, 32-37 and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al. (6,120,523). Crocker et al. discloses a focalized intraluminal balloon.

Regarding claims 27-29, 32-37 and 65-68, Crocker et al. discloses a medical balloon (18) having a longitudinal axis and proximal (26) and distal (28) ends, the balloon formed of a polymer material (col 6, ln 25-40), the balloon connecting to a coaxial shaft (37) at a proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof (39), and having a central body wall portion (30) between each end spaced apart from the balloon ends and connected thereto by means

Art Unit: 3763

of tapering proximal and distal wall (38, 42) portions, respectively, wherein the balloon further comprises a lumen (32) extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon (Figures 1-4).

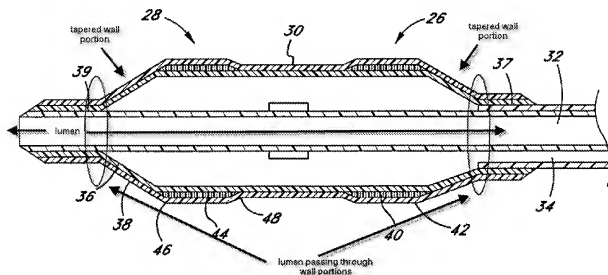


FIG. 2

Crocker et al. discloses a polymeric (cross-linked polyethylene, col 7, ln 35-55) balloon and is a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (36, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change. Examiner asserts that the radiation cured polymer is a product by process limitation in which the resultant radiation cross-linked product is indistinguishable from the heat cross-linked polyethylene of Crocker et al.

Claim Rejections - 35 USC § 102

Claims 27-29, 32-35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin (6,132,824). Hamlin discloses a multi-layer catheter balloon.

Regarding claims 27-29, 32-35, and 38 Hamlin discloses a medical balloon (40, 58) having a longitudinal axis and proximal (near 64) and distal (near 50) ends, the balloon formed of a polymer material (col 2, ln 30-50), the balloon connecting to a coaxial shaft (50) at a proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof (62), and having a central body wall portion (near 68) between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall (Figures 5-6) portions, respectively, wherein the balloon further comprises a lumen (52) extending longitudinally there through, said lumen passing through the proximal and distal wall portions of the balloon (Figures 5-6). Hamlin discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprised of a multi-layer polymeric film (64, 66, 68) wherein a first (64, 66) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 5-6).

Claim Rejections - 35 USC § 102

Claims 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Boussignac et al. (5,000,734). Boussignac et al. discloses a probe intended to be introduced within a living body.

Regarding claims 63-64, Boussignac et al. discloses a medical balloon (1) (Figures 1-2, 4) having a longitudinal axis (along 7) and proximal and distal ends (3,4), the balloon formed of polymer material (col 3, ln 25-35), the balloon connecting to a coaxial shaft (3) at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall (near 1) portion connected with tapering wall portions (near 5a,5b), wherein the balloon comprises a lumen (11) extending therethrough, the lumen spaced apart from the coaxial shaft (Figure 3).

Claim Rejections - 35 USC § 102

Claim 65 is rejected under 35 U.S.C. 102(b) as being anticipated by White, Jr. (4,327,734). White, Jr. discloses a therapeutic method of use for a detachable balloon assembly.

Regarding claim 65, White, Jr. discloses a balloon (20) comprising a balloon body (38) having a proximal and distal end, and the balloon comprising circumferential elastic bands (46) at the proximal end or distal end of the balloon body, the elastic bands (46) in their rest configuration have a smaller diameter than the balloon body in its rest configuration (Figure 1) versus the inflated configuration (Figures 2-3) (Figures 1-3).

Claim Rejections - 35 USC § 102

Claims 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (6,007,517). Anderson discloses a rapid exchange/perfusion angioplasty catheter.

Regarding claims 63-64, Anderson discloses a medical balloon (3) catheter (1) (Figures 1C, 2A, 3A, 10A and 11A) having a longitudinal axis (along 9) and proximal and distal ends (near 5, 6), the balloon formed of polymer material, the balloon connecting to a coaxial shaft (2) at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall (near 7) portion connected with tapering wall portions (near 5 and 6), wherein the balloon comprises a lumen (7) extending therethrough, the lumen spaced apart from the coaxial shaft (Figures 3A and 11A).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-31 are rejected under 35 U.S.C 103(a) as being unpatentable over Crocker et al. Crocker et al. meets the claim limitations as described above except for the specific embodiment being used in with a stent or with a rapid exchange catheter.

Regarding claims 30-31, Crocker et al. teaches a specific medical balloon structure that is disclosed of being used with rapid exchange and for delivery of stents to the vascular system (col 3, ln 40-70, col 4, ln 40-70, see summary of invention).

At the time of the invention, it would have been obvious to use the medical balloon as disclosed by the various embodiments and the disclosure of Crocker et al. in order to achieve a versatile controllable balloon element. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Crocker et al. (cols 1-2).

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of the lumen by incorporation of the lumen axis, i.e. that the lumen axis is offset from the central longitudinal axis of the balloon. Examiner further suggests clarification of the "at rest areas" by defining which layer is the outermost layer (i.e. first/second) or by defining the change in surface area based upon layer interactions.

Response to Arguments

Applicant's arguments filed 07/14/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the references fail to show a balloon with a lumen "extending through the tapering proximal and distal wall portions

(claims 27 and 63)", a balloon with multiple layers with the "first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface" (claim 32), the balloon having "elastic bands" (claim 65) and that the balloon is wherein the balloon is formed of a radiation cured polymerizable composition (claim 63).

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Regarding claims 27 and 63, Examiner asserts that the balloon pictured in Figure 2 meets the claim limitations as claimed. The lumen (32) of Crocker et al. passes *through the tapering distal and proximal wall portions* (38, 42) of the balloon. Examiner asserts that the language as claimed is insufficient to overcome the prior art of record, the broadest reasonable of the definition of "extending through" is "passing or extending from one end, side, or surface to another" "*through.*" *The American Heritage® Dictionary of the English Language. 2007.* Therefore Examiner asserts that the lumen (32) of Crocker et al. indeed passes through the tapering distal and proximal portions as claimed.

Regarding claim 32, Examiner asserts that the first (36) and second balloon (48) layers of Crocker et al. meet the claimed limitations of "having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller

than the at-rest area of said second layer inner surface." Examiner asserts that the outer surface of the first layer (36) has a smaller surface area than the inner surface of the second layer (48) because of the stretched areas (near 44 and 40) which are present to accommodate the expansion limiting bands and that the second layer must cover the first layer.

Regarding claim 65, Examiner asserts that the bands of Crocker et al. as disclosed as "substantially non-distensible" materials (col 5, ln 20-30), therefore the materials (nylon, plyamide, polyethylene and PET) do have some elasticity and can be considered to fall under the broadest reasonable definition of an "elastic" material (easily resuming original shape after being stretched or expanded; flexible, see *elastic*. (2007). In *The American Heritage® Dictionary of the English Language*. Since the materials listed do have expansion recovery and are termed as "expansion limiting bands" they facilitate and undergo some expansion and recovery during balloon inflation and deflation states. Examiner suggest Applicant further clarify the claim with specific elastic characteristics.

Regarding claim 63, Examiner asserts that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also when the reference teaches a product that appears to be

the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983). Therefore the balloons of Anderson (3) and Boussignac et al. (5) are composed of several different materials of which polyethylene is disclosed, Examiner considers the radiation curing of polyethylene to result in an indistinguishable product from a polyethylene product formed via a different means of curing (such as heat). If Applicant wishes to gain patentability of this process Applicant must direct method/process claims towards this specific claim scope.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/17/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763